AUDIT REPORT FOR HONDURASJUNE 11 THROUGH JUNE 18, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the Honduran meat inspection system from June 11 through June 18, 2001. Two establishments were certified to export meat to the United States; both were audited. Both establishments were conducting beef slaughter and boning operations.

The last audit of the Honduran meat inspection system was conducted in March 2000. The same two establishments were audited: both were acceptable. The following major concerns were identified at that time:

- 1. Fecal contamination and hair was found on ready-to-ship beef tails in one establishment,
- 2. Ready-to-ship beef esophagi in one establishment had not been completely split,
- 3. Product destined for export in one establishment was not differentiated from product for domestic use,
- 4. Product-contact equipment was contaminated through being placed on a floor,
- 5. Samples for Salmonella species sampling were not random in one establishment,
- 6. Critical limits had not been established for one critical control point in one establishment, and were too general in the other establishment.

At the time of this audit, Honduras was eligible to export meat products to the United States. A restriction was in place that pork must be cooked to be eligible; only beef products were being exported to the U.S. There were no meat exports to the U.S. during calendar year 2000. From January 1 through May 31, 2001, Honduras exported 637,200 lbs. of beef products to the U.S. One lot (44,400 lbs., or 6.9%) was rejected at the U.S. port of entry for processing defects.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Honduran national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments and the third was the visits to the farms where livestock are raised and fed. The fourth was a visit to a laboratory performing analytical testing of field samples for the national residue testing program and the culturing of field samples for the presence of microbiological contamination with *Salmonella* species.

Honduras's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During the on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in both establishments. Details of the audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

As stated above, the concerns that had been identified during the last audit of the Honduran meat inspection system, conducted in March 2000, were the following:

- 1. Fecal contamination and hair was found on ready-to-ship beef tails. This had been corrected.
- 2. Ready-to-ship beef esophagi in one establishment had not been completely split. This had been corrected.
- 3. Product destined for export in one establishment was not differentiated from product for domestic use. This was again found in one establishment: it was a repeat deficiency.
- 4. Product-contact equipment was contaminated through being placed on a floor. This had been corrected.
- 5. Samples for Salmonella sampling were not random in one establishment. This had been corrected.
- 6. Critical limits had not been established for one critical control point in one establishment, and were too general in the other establishment. This had been corrected.

Entrance Meeting

On June 11, 2001, an entrance meeting was held at the Tegucigalpa offices of the Honduran National Service of Animal and Plant Health (SENASA), and was attended by Dr. Pedro Mendoza, Chief of Official Inspection Service of Animal Products (SIOPOA); Dr. Francisco

Ordonez, Regional Supervisor of SIOPOA; Dr. Pedro Barahona, Chief of the Meat Section of SIOPOA; Dr. Max Rivera, Director of National Residue Laboratory (ANEDEC); Mr. Raul Saybe, Chief of the Dairy Section of SIOPOA; Mr.Rafael Navarro Paz, interpreter; and Dr. Suresh P. Singh, International Audit Staff Officer, FSIS. Topics of discussion included the following:

- 1. Compliance and enforcement,
- 2. Training programs for inspection service employees,
- 3. Various requests from International Policy Division, e.g. species verification, a residue questionnaire sent to all countries exporting meat to the U.S., microbiological testing programs, and laboratory responsibilities,
- 4. Details of on-site visits to establishments, a farm, and a feed mill and of records audits, and
- 5. Details of the daily itinerary.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the Honduran inspection system in March 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the Auditor") observed and evaluated the process.

Since there were only two certified establishments, both establishments were visited and the records were audited. The records audits focused primarily on food safety hazards and included the following:

- Internal review reports,
- Supervisory visits to establishments that were seeking certification to export to the U.S..
- Training records for inspectors and laboratory personnel,
- Label approval records such as generic labels,
- New laws and implementation documents such as regulations, notices, directives and guidelines,
- Sampling and laboratory analyses for residues,
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* species testing,
- Sanitation, slaughter and processing inspection procedures and standards,
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials,

- Export product inspection and control, including export certificates, and
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Honduras as eligible to export meat products to the United States were full-time SENASA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

The two certified establishments (Establishment numbers 4 and 12) that were certified to export meat and meat products to the United States at the time were audited. Both establishments were visited for on-site audits. In both of the establishments, both SENASA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audit, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

- 1. Government oversight of accredited, approved, and private laboratories.
- 2. Intra-laboratory quality assurance procedures, including sample handling.
- 3. Methodology.

The Residue National Laboratory (ANEDEC) in Tegucigalpa was audited on June 18, 2001. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Honduras's microbiological testing for *Salmonella* species was being performed in government laboratories. One of these, the Laboratorio Nacional De Analsis De Residuos Quimicos y Microbiologicos (LANAR) was audited. The auditor determined that the system met the criteria established for the use of government laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

- 1. The laboratory was accredited/approved by the government.
- 2. The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
- 3. Results of analyses were being reported simultaneously to the government and to the establishments.

Establishment Operations by Establishment Number

Both establishments 4 and 12 were conducting beef slaughter and boning operations.

SANITATION CONTROLS

Based on the on-site audits of the establishments, Honduras's inspection system had controls in place for water potability, chlorination procedures, back-siphonage prevention, handwashing facilities, sanitizers, pest control, temperature, lighting, operations and inspectors' work space, ventilation, over-product ceilings and equipment, dry storage areas, ante-mortem facilities, welfare facilities, outside premises, personal dress, habits, and hygiene procedures, cross-contamination prevention equipment sanitizing, product handling and transportation, maintenance, pre-operational and operational sanitation, and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

Product Handling and Storage

In establishment 12, boxed product destined for U.S. export was not marked as such and was not segregated from product for the domestic market. This was a repeat finding from the previous FSIS audit in March 2000. The establishment management the deficiency and gave assurances that product for export to the U.S. would be henceforth stored separately from product intended for domestic consumption.

Maintenance

There were several instances of neglected maintenance: some floors were broken and in need of repair; freezer doors were damaged, and rust was observed on rails in carcass coolers. The establishment management agreed to schedule the needed repairs promptly.

ANIMAL DISEASE CONTROLS

Honduras's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Honduras's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Honduran inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures, storage and use of chemicals, and control of veterinary pharmaceuticals and feed additives. A beef cattle farm, a feed mill, and a veterinary drug and vaccine store were visited during this audit to collect information and data regarding animal husbandry practices.

The Auditor verified that Honduras's responses to an in-depth questionnaire regarding residue controls, sent to all countries exporting meat to the United States, were still valid.

SLAUGHTER/PROCESSING CONTROLS

The Honduran inspection system had controls in place to ensure adequate humane handling and slaughter, packaging materials, label approvals, inspector monitoring, and processing (boning and cutting) equipment and records.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements.

Testing for Generic E. coli

Honduras had adopted the FSIS regulatory requirements for generic *E. coli* testing with the following equivalent different requirements:

1. SAMPLE COLLECTOR. Government takes samples.

- There is a clearly written sampling plan with instruction for sample collection and processing that will be universally followed.
- The government has a means of ensuring that sample collection activities are appropriate.
- The government uses the test results to verify establishment slaughter, processing and dressing controls for fecal contamination.

2. LABORATORIES. Government laboratories.

- The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.
- Results of analyses including all permanently recorded data and summaries are reported promptly to the establishment.

Both of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, with the exception that the location for carcass sampling for generic *E. coli* was not specified in the written procedure. Establishment management officials gave assurances that this would be corrected promptly.

ENFORCEMENT CONTROLS

Inspection System Controls

The SENASA inspection system controls [ante-and post-mortem inspection procedures and dispositions; control of restricted product and inspection samples; control and disposition of dead; dying; diseased or disabled animals; boneless meat reinspection; shipment security, including shipment between establishments; monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans); inspection supervision and documentation; the importation of only eligible livestock or poultry from other countries (i.e.; only from eligible countries and certified establishments within those countries); and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for Salmonella Species

Both establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Honduras had adopted the FSIS regulatory requirements for *Salmonella* species testing. The *Salmonella* species testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification

At the time of this audit, Honduras was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements.

MONTHLY REVIEWS

These reviews were being performed by the Honduran equivalent of Circuit Supervisors. All were veterinarians. Dr. Francisco Ordonez was in charge of these reviews.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were announced in advance and were conducted by individuals, at least once monthly, and sometimes more often. The records of audited establishments were kept in the inspection offices of the individual establishments.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a supervisor is empowered to conduct an in-depth review, and the results are reported to SENASA for evaluation; they formulate a plan for corrective actions and preventive measures to be completed before relistment.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Honduras's internal review program as a whole.

Enforcement Activities

On February 15, 2000, new laws were enacted to combine domestic and export rules. Enforcement cases were handled by SENASA.

Exit Meetings

An exit meeting was conducted in Tegucigalpa on June 18, 2001. The Honduran participants were; Dr. Francisco Rodas, Sub-Director of SENASA; Dr. Perdo Mendoza, Chief of SIOPOA; Dr. Max Rivera, Director of the ANEDEC Laboratory; Mr. Rafael Navarro Paz, interpreter; and Dr. Suresh P. Singh, International Audit Staff Officer, FSIS. The following topics were discussed:

- 1. The results of the on-site audits. The Honduran officials gave assurances that the inspection service officials in the field would monitor the establishments to ensure that the deficiencies found would be adequately addressed and corrected.
- 2. The results of the laboratory audit: the findings were satisfactory.
- 3. Information on the training program for inspection personnel was provided.

CONCLUSION

The inspection system of Honduras was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Two establishments were audited: both were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Suresh P. Singh International Audit Staff Officer (signed) Dr. Suresh P. Singh

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for generic *E. coli* testing.
- D. Data collection instrument for Salmonella species testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

	1.Written	2. Pre-op	3. Oper.	4. Contact	5. Fre-	6. Respons-	7. Docu-	8. Dated
	program	sanitation	sanitation	surfaces	quency	ible indiv.	mentation	and signed
Est. #	addressed	addressed	addressed	addressed	addressed	identified	done daily	
4	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	V	$\sqrt{}$
12	V			$\sqrt{}$	V	V		

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment had conducted a hazard analysis.
- 3. The analysis includes food safety hazards likely to occur.
- 4. The analysis includes the intended use of or the consumers of the finished product(s).
- 5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 8. The plan describes corrective actions taken when a critical limit is exceeded.
- 9. The HACCP plan was validated using multiple monitoring results.
- 10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
- 11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
- 12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Haz- ard an- alysis conduct -ed	3. All hazards ident- ified	4. Use & users includ- ed	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are des- cribed	9. Plan valida- ted	10.Ade- quate verific. proced- ures	11.Ade- quate docu- menta- tion	12. Dated and signed
4	√	√	√	√	√	√	√	√	√	√	√	V

Data Collection Instrument for Generic E. coli Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written procedure for testing for generic E. coli.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

	1.Writ-	2. Samp-	3.Samp-	4. Pre-	5. Samp-	6. Pro-	7. Samp-	8. Using	9. Chart	10. Re-
	ten pro-	ler des-	ling lo-	domin.	ling at	per site	ling is	AOAC	or graph	sults are
Est. #	cedure	ignated	cation	species	the req'd	or	random	method	of	kept at
			given	sampled	freq.	method			results	least 1 yr
4			no		\checkmark				$\sqrt{}$	$\sqrt{}$
12			$\sqrt{}$		\checkmark				$\sqrt{}$	$\sqrt{}$

Data Collection Instrument for Salmonella testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations	
4	V	√	N/A	√ ·	√	√	
12	V	V	N/A	V	√	V	

13